UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,441	04/04/2007	Bernadette Verneau	047578/314794	5355

826 7590 05/27/2008

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
KASSA, TIGABU	

ART UNIT	PAPER NUMBER
4161	

MAIL DATE	DELIVERY MODE
05/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,441	VERNEAU, BERNADETTE	
	Examiner	Art Unit	
	TIGABU KASSA	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 7/26/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

This application is a 371 of PCT/FR05/00166 filed on 01/26/2005, which is filed at national stage 04/04/2007.

Claims 1-10 and 12 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Priority

The earliest effective filing date afforded for the instantly claimed invention, has been determined to be 01/26/2005, the filing date of the PCT/FR05/00166.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 26, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim objections

Claim 8 is objected to because of the following informalities: Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention .

1. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing or lowering excess body fat in human subjects, does not reasonably provide enablement for the prevention of obesity in human subjects. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

2. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope of breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claim is broader in scope than the enabling disclosure. The specification discloses, without more, a method of reducing or lowering excess body fat in human subjects. However, Applicant is purporting to prevent obesity.

2) Nature of the invention

The nature of the invention is directed to a slimming composition and method of reducing or lowering excess body fat in human subjects.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators conducting scientific research and development in this particular area possess M.D. and/or Ph.D. in a scientific discipline such as medicinal chemistry, biochemistry, pharmacology, biology, organic synthetic chemistry or the like.

4) State of, or the amount of knowledge in, the prior art

The art teaches that compositions comprising conjugated linoleic acid and caffeine and other agents that can cause lipolysis, are likely to be recognized as means of lowering, reducing, and treating excess body fat or cellulite in animal and human subjects (Saper et al., Common dietary supplements for weight loss, American Family physician, 2004, 70, 1731-1738).

5) Level or degree of predictability, or lack thereof, in the art

A high degree of unpredictability existed in the state of the prior art regarding how to prevent obesity. Many risk factors cannot be controlled in obesity. The methods of prevention are linked to actions that need to be taken before it occurs. Choices widely vary on individual bases on such subjects like changing in eating habits, the amount of food that is served, the amount of daily exercise, and other factors considered to be healthy lifestyle, which may also reduce the incidence of obesity. However, medications and weight loss supplements are considered to be one type of treatment of obesity once

it occurs (http://www.nhlbi.nih.gov/health/dci/Diseases/obe/obe_causes.html, May 2008).

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how to use the claimed subject matter in order for the claim to be enabled with regard to the full scope of the claimed invention. Although, the instant specification discloses a method of lowering, reducing, and treating excess body fat or cellulite in human subjects by taking the claimed composition (a study that required 32 subjects for one month), the specification also discloses that the slimming composition was taken by people with excess weight (instant specification, page 5). Thus, by Applicant's own disclosure, the instant method cannot prevent obesity.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to prevention of obesity.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation, to reasonably and accurately determine whether the composition and corresponding method of the instant application does in fact prevent obesity.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with the lack of scientific data and working embodiments regarding the

prevention of obesity, one of ordinary skill in the art would therefore be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether said method would prevent obesity or not.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 5-6, 9-10, and 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Halvorsen et al (U.S. Patent Application Publication N. 2001/0041708, published November 15, 2001) (hereinafter Halvorsen et al. '708).

3. Instant claim 1 recites a composition comprising conjugated linoleic acid and caffeine in mass ratio between 1 and 15 and in further limitation as recited in claim 2 between 1 and 6, which is formulated with an appropriate carrier for use via the oral route in order to loss weight.

4. Halvorsen et al. '708 discloses compositions and methods for treating and preventing cellulite by using the composition comprising conjugated linoleic acid (from about 0.1% to about 10% by weight) (paragraph [0013]) and caffeine (from about 0.05% to 20% by weight) (paragraph [0053]) and other additional ingredients through administration via the oral route (paragraph [0020] and [0021]) or as topical form or skin care product (paragraph [0021]). Furthermore, based on calculations done by examiner

by converting the disclosed weight % values to mass, the conjugated linoleic acid/caffeine mass ratio is between 0.005 and 200, which reads on claims 1 and 2.

5. Instant claim 5 recites possible forms of the composition being in powdered form, in liquid form. Halvorsen et al. '708 discloses different vehicles for delivering the composition can include liquid or solid emollients, solvents, humectants, thickeners and powders (paragraph [0038], which reads on claim 5.

6. Instant claim 9 recites possible administration forms of the composition as dietary supplement, a dietetic composition or a cosmetic composition.

7. Halvorsen et al. '708 also discloses the composition can be formulated for either oral administration (paragraph [0020] and [0021]) or topical (cosmetic) (paragraph [0021]) form to be applied to the skin for cellulite prevention or reduction, which reads on claim 9.

8. Instant claim 10 recites a method of increasing weight loss through administering the claimed composition via the oral route.

9. Halvorsen et al. '708 also discloses that the composition is used to reduce or eliminate cellulite or fat build-ups through taking an effective amount of the formulation via the oral route (paragraph [0020]). Halvorsen et al. '708 also discloses methods for treating and preventing cellulite by administering a safe and effective amount of said composition in topical form (paragraph [0012]). Additionally, Halvorsen et al. '708 mentions that the composition demonstrates a slimming and "rejuvenating" effects on appearance (paragraph [0022]), which reads on claim 10 and 12.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

4. Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halvorsen et al (U.S. Patent Application Publication N. 2001/0041708, published

November 15, 2001) (hereinafter Halvorsen et al. '708) in view of Alviar et al. (U.S. patent No. 6,413, 545; Issued July 2, 2002) (hereinafter Alviar et al. '545). The examiner notes that the Alviar et al. '545 reference was provided by the applicant in the information disclosure statement (IDS) filed on 7/26/2006.

5. Halvorsen et al. '708 discloses composition comprising conjugated linoleic acid (from about 0.1% to about 10% by weight) (paragraph [0013]) and caffeine (from about 0.05% to 20% by weight) (paragraph [0053]) and other additional ingredients as a slimming agent to be administered either as oral formulation or topical form applied on the skin. This differs from the claimed invention in the instant application that Halvorsen et al. '708 doesn't disclose the additional ingredients, pharmaceutical excipients, and various possible forms of formulations as recited in claims 3-4 and 6-8 of the instant application.

6. However, Alviar et al. '545 discloses a dietary composition effective for managing body weight comprising different supplements including conjugated linoleic acid (column 5, lines 22-33) and a kola nut extract used as a source of caffeine (column 6, lines 5-8), which is formulated with appropriate carriers to be taken through the oral route. Specifically, Alviar et al. '545 discloses the additional ingredients, pharmaceutical excipients, and various possible forms of formulations that are recited in claims 3-4 and 6-8 of the instant application as follows:

7. Instant claim 3 recites the composition comprises lecithin and colloidal silica. Alviar et al. '545 discloses the diet composition comprises silicone dioxide fine powder (column 10, Table C) and lecithin (column 11, Table E), which reads on claim 3.

8. It would have been prima facie obvious to modify the caffeine and CLA composition taught by Halvorsen et al., by adding lecithin and colloidal silica as taught by the Alviar et al., because lecithin is a known digestible surfactant and emulsifier of natural origin (The Merck Index definition, Fourteenth Edition) and colloidal silica is also a known surfactant used for flocculating, coagulating, dispersing, stabilizing etc (http://www.azom.com /details.asp?ArticleID+1385).

9. Instant claim 4 recites in further limitation the composition comprises a green coffee extract and/ or chromium chloride. These two ingredients are a source of caffeine and chromium (III), respectively. As it is known by the skilled in the art and also the disclosure by applicant's own specification caffeine and chromium are also weight loss agents, which can be found from different sources, and specifically chromium in different salt forms. Alviar et al. '545 also discloses that the diet composition also comprises caffeine from kola nut extract (column 6, lines 5-8) and chromium picolinate another salt form of chromium (column 10, Table C), which is equivalent to chromium chloride.

10. It would have been prima facie obvious to modify the caffeine and CLA composition taught by Halvorsen et al., by adding a green coffee extract which is a source of caffeine and chromium chloride as taught by the Alviar et al., because the green coffee extract is solely an obvious source of caffeine, which can be also found from other sources like kola nut extract as taught by Alviar et al. Chromium chloride is one salt form of chromium, which also can be replaced by other salts like chromium picolinate in Alviar et al.. One of ordinary skill in the art at the time of the instant

application was filled would have had a reasonable expectation of success in doing so since these ingredients are known sources of caffeine and chromium, which are also known weight loss agents too.

11. Instant claims 6-7 recite various possible carrier forms for taking the slimming composition like in the form of soluble coffee, tablets, gelatin capsules, capsules or sachets of powder. Examiner interprets "in the form of soluble coffee" as either in liquid or solid form. Alviar et al. '545 discloses that "the diet composition can be produced as powder, liquid, syrup, emulsion, suspension, and any other available substance to produce finished food products, for example, in the form of biscuits, cakes, cookies, weight loss candy bars, or ingredients of beverages, pasta, or other solid, liquid, or powder carrier for the composition" (column 6, lines 24-40), which reads on claims 6-7 in the instant Alviar et al. '545 discloses that the diet composition can be produced in the form of gelatin capsules, hard capsules, pills, resins, or any other compressed material. Based on the disclosure in Alviar et al. '545 it is possible to interpret that the soluble coffee form as a finished food product either liquid or solid beverage form. Hence, Alviar et al. '545 disclosure reads on claims 6-7.

12. It would have been prima facie obvious to prepare the caffeine and CLA composition taught by Halvorsen et al. in powdered or in liquid form as taught by Alviar et al. for delivering the claimed composition.

13. One of ordinary skill in the art would have been motivated to do this because powder and liquid forms have been shown to be a known form of pharmaceutical carriers for delivering drug formulations as reasonably used by Alviar et al. and also

suggested by Halvorsen et al. (paragraph [0036]). Furthermore, the other disclosed forms like tablets, gelatin capsules, capsules or sachets of powder are known pharmaceutical forms as in reasonably used by Alviar et al. (column 6, lines 24-40).

14. Instant claim 8 recites in further limitations the contents of the slimming composition caffeine from different sources, conjugated linoleic acid, chromium chloride, and common pharmaceutical and nutraceutical agents lecithin and colloidal silica. In the instant application there are 72 mg of caffeine, 310 mg of conjugated linoleic acid, 0.064 mg of chromium chloride, 30 mg of lecithin, and 30 mg of colloidal silica. If the given weights are converted to % weight there is 10.3% conjugated linoleic acid, 2.4% caffeine, 1% lecithin, 1% colloidal silica, and 0.00042% chromium chloride. Alviar et al. '545 also discloses between 15.5-79.6 % conjugated linoleic acid, 0.38-1.25% caffeine, 0.02-0.11 % chromium picolinate, 0.5% lecithin, and 0.2% colloidal silica by weight.

15. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a slimming composition comprising conjugated linoleic acid, caffeine, lecithin, chromium chloride, and colloidal silica as demonstrated by Alviar et al., because weight loss compositions comprising conjugated linoleic acid and caffeine and other known pharmaceutical excipients are well known among those skilled in the art. Based on examiner's interpretation the specific mass and mass ratios given for the slimming agents and pharmaceutical excipients in the instant application as recited in claim 8 is merely an optimization of previously known parameters disclosed by Alviar et al. '545 and Halvorsen et al. '708.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu kassa 5/19/08

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161